

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF TEXAS  
HOUSTON DIVISION

UNITED STATES OF AMERICA

Plaintiff,

v.

KEVIN XU

Defendant.

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CRIMINAL NO.

18 U.S.C. § 371

18 U.S.C. § 2320(a)

21 U.S.C. § 331(a)

21 U.S.C. § 331(i)

**H 07 362**

United States Courts  
Southern District of Texas  
FILED

AUG 23 2007

Michael N. Milby, Clerk

INDICTMENT

THE GRAND JURY CHARGES:

COUNT ONE

(Conspiracy – 18 U.S.C. § 371)

A. INTRODUCTION

At all times material to this indictment:

1. The United States Food and Drug Administration (FDA) is the agency of the United States charged with the responsibility of protecting the health and safety of the American public by ensuring, among other things, that drugs sold for administration to humans bear labeling containing true and accurate information. The FDA's responsibilities include regulating the labeling and distributing of prescription drugs shipped or received in interstate commerce.

2. Under the Food Drug and Cosmetic Act, the definition of a "drug" includes articles which (1) are intended for use in the diagnoses, cure, mitigation, treatment or prevention of disease in man, and (2) are intended to affect the structure or function of the body of man. Due to the toxicity and other potential harmful effect, certain drugs are not considered safe for use except for use under the supervision of a practitioner licensed by law to administer such drugs.

These drugs are known as prescription drugs.

3. Zyprexa was a prescription drug product that had been approved by the FDA for distribution within the United States. Zyprexa is used in the treatment of schizophrenia.

4. Eli Lilly Corporation (Lilly) had the exclusive right to manufacture Zyprexa for distribution within the United States.

5. The name “Zyprexa” was a trademark owned by Lilly and is registered in the principal registry in the United States Patent and Trademark Office.

6. Tamiflu was a prescription drug product that had been approved by the FDA for distribution within the United States. Tamiflu is used in the treatment of influenza.

7. Roche Corporation (Roche) had the exclusive right to manufacture Tamiflu for distribution within the United States.

8. The name “Tamiflu” was a trademark owned by Roche and is registered in the principal registry in the United States Patent and Trademark Office.

9. Plavix was a prescription drug product that had been approved by the FDA for distribution within the United States. Plavix is used in the treatment of blood clots.

10. Bristol-Myers Squibb and Sanofi Aventis had the exclusive right to manufacture Plavix for distribution within the United States.

11. The name “Plavix” was a trademark owned by Bristol-Myers Squibb and Sanofi Aventis and is registered in the principal registry in the United States Patent and Trademark Office.

12. Casodex was a prescription drug product that had been approved by the FDA for distribution within the United States. Casodex is used in the treatment of prostate cancer.

13. Astra Zeneca had the exclusive right to manufacture Casodex for distribution within the United States.

14. The name “Casodex” was a trademark owned by Astra Zeneca and is registered in the principal registry in the United States Patent and Trademark Office.

12. Aricept was a prescription drug product that had been approved by the FDA for distribution within the United States. Aricept is used in the treatment of Alzheimers.

13. Pfizer Pharmaceuticals (Pfizer) had the exclusive right to manufacture Aricept for distribution within the United States.

14. The name “Aricept” was a trademark owned by Pfizer and is registered in the principal registry in the United States Patent and Trademark Office.

15. The Food Drug and Cosmetic Act also regulates the importation, delivery, distribution and receipt of prescription drugs in interstate commerce. Under the Act, a prescription drug is deemed misbranded if its labeling is false or misleading in any particular manner. A prescription drug is also deemed to be counterfeit if it bears a trademark without the authorization of the registrant of the trademark.

16. Kevin Xu, defendant herein, was the owner and operator of Orient Pacific International, a corporation located in the Peoples Republic of China that distributed counterfeit pharmaceutical drugs.

## **B. THE CONSPIRACY**

17. Beginning in or about July, 2006 and continuing thereafter to on or about July, 2007, in the Houston Division of the Southern District of Texas and elsewhere, defendant,

KEVIN XU

did knowingly, intentionally, and willfully combine, conspire and confederate and agree with other persons unknown to the grand jury to commit certain offenses against the United States, namely:

- a. To traffic and attempt to traffic in counterfeit goods in violation of Title 18, United States Code, Section 2320(a).
- b. To violate the Food, Drug and Cosmetic Act, namely, with the intent to defraud and mislead, cause the introduction and delivery for introduction of prescription drugs into interstate commerce that are misbranded, in violation of Title 21, United States Code, Section 331(a) and 333(a)(2).
- c. To violate the Food, Drug and Cosmetic Act, namely, with the intent to defraud and mislead, cause the counterfeiting of trademarks Viagra and Cialis in violation of Title 21, United States Code, Section 331(I), 333(a)(2)

**C. OBJECT OF THE CONSPIRACY**

18. It was the object of the conspiracy for the defendant and others to unlawfully enrich themselves by the exportation of pharmaceutical drug products that bore the trademarks Zyprexa, Tamiflu, Casodex, Plavix and Aricept without the authorization of manufacturer of said drugs, and thereafter resell the drugs to the public.

**D. MANNER AND MEANS**

The manner and means of the conspiracy included, but were not limited to the following:

19. Defendant Kevin Xu would and did use the internet to advertise the sale of

counterfeit pharmaceuticals.

20. Defendant KEVIN XU would and did receive orders for pharmaceutical drugs such as Zyprexa, Tamiflu, Casodex and Aricept.

21. Defendant KEVIN XU would and did cause individuals residing in the Republic of China to place counterfeit Zyprexa, Tamiflu, Casodex, Plavix and Aricept in interstate commerce by delivering the drugs to a common carrier for airfreight shipment to the United States.

22. Defendant KEVIN XU would and did cause individuals to ship counterfeit pharmaceuticals from China to United States. The pharmaceuticals were counterfeit in that they were falsely represented to be Tamiflu capsules and Zyprexa, Casodex, Plavix and Aricept pills. The counterfeit capsules and pills bore the same mark, shape and appearance as the genuine Zyprexa, Tamiflu, Casodex, Plavix and Aricept capsules and pills.

23. Defendant KEVIN XU would and did cause individuals to ship misbranded pharmaceuticals from China to the United States. The pharmaceuticals were misbranded in that

- a. The labeling on the blister pack containing the pills falsely represented that they contained genuine Zyprexa, Tamiflu, Casodex, Plavix and Aricept pharmaceutical products; and
- b. The pills were manufactured and dispensed from a non-FDA approved facility.

#### **OVERT ACTS**

24. In furtherance of the conspiracy and to effect the objects thereof, the following Overt Acts, among others, were committed in the Southern District of Texas:

- (1) On or about December 8, 2007, defendant KEVIN XU, using an internet email address, sent an email listing the tracking numbers connected to the sale of counterfeit pharmaceuticals.

(2) On or about April 9, 2007, defendant KEVIN XU caused coconspirators residing in the Peoples Republic of China to place in interstate commerce approximately 183 10-count blister strips containing counterfeit Tamiflu for shipment to the United States.

(3) On or about April 9, 2007 defendant KEVIN XU caused coconspirators residing in the Peoples Republic of China to place in interstate commerce approximately 20 30-count boxes containing counterfeit Casodex in blister strips for shipment to the United States.

(4) On or about April 22, 2007, defendant KEVIN XU caused coconspirators residing in the Peoples Republic of China to place in interstate commerce approximately 160 7-count blister strips containing counterfeit Zyprexa for shipment to the United States.

(5) On or about June 7, 2007 defendant KEVIN XU caused coconspirators residing in the Peoples Republic of China to place in interstate commerce approximately 20 28-count boxes containing counterfeit Plavix in blister strips for shipment to the United States.

**In violation of Title 18, United States Code, Section 371.**

**COUNT TWO**  
**(Misbranded Drugs)**

1. On or about December 8, 2006, in the Houston Division of the Southern District of Texas, the defendant,

KEVIN XU

with the intent to defraud and mislead, caused the introduction and delivery for introduction into interstate commerce drugs that were misbranded, namely a shipment containing blister strips of Tamiflu capsules that were labeled in a manner to falsely represent that the blister strips

contained the genuine Tamiflu pharmaceutical drug.

**In violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).**

**COUNT THREE**  
**(Misbranded Drugs)**

1. On or about January 3, 2007, in the Houston Division of the Southern District of Texas, the defendant,

KEVIN XU

with the intent to defraud and mislead, caused the introduction and delivery for introduction into interstate commerce drugs that were misbranded, namely a shipment containing blister strips of Zyprexa pills that were labeled in a manner to falsely represent that the blister strips contained the genuine Zyprexa pharmaceutical drug.

**In violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).**

**COUNT FOUR**  
**(Misbranded Drugs)**

1. On or about February 20, 2007, in the Houston Division of the Southern District of Texas, the defendant,

KEVIN XU

with the intent to defraud and mislead, caused the introduction and delivery for introduction into interstate commerce drugs that were misbranded, namely a shipment containing blister strips of Plavix pills that were labeled in a manner to falsely represent that the blister strips contained the

genuine Plavix pharmaceutical drug.

**In violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).**

**COUNT FIVE**  
**(Trafficking in Counterfeit Goods)**

1. On or about December 8, 2006, in the Houston Division of the Southern District of Texas, the defendant,

KEVIN XU

aided and abetted by others unknown to the Grand Jury, did intentionally traffic and attempt to traffic in goods, namely, pharmaceutical drugs, and knowingly used a counterfeit mark on and in connection with such goods, that is, the Zyprexa trademark used to identify a pharmaceutical product marketed by Eli Lilly, which counterfeit mark was identical with and substantially indistinguishable from the genuine mark in use and registered for that good on the principle register in the United States Patent and Trademark Office, and the use of which mark was likely to cause confusion, mistake and deception regarding said mark.

**In violation of Title 18, United States Code, Sections 2320(a) and 2.**

**COUNT SIX**  
**(Trafficking in Counterfeit Goods)**

1. On or about January 3, 2007, in the Houston Division of the Southern District of Texas, the defendant,

KEVIN XU



aided and abetted by others unknown to the Grand Jury, did intentionally traffic and attempt to traffic in goods, namely, pharmaceutical drugs, and knowingly used a counterfeit mark on and in connection with such goods, that is, the Tamiflu trademark used to identify a pharmaceutical product marketed by Roche Corporation, which counterfeit mark was identical with and substantially indistinguishable from the genuine mark in use and registered for that good on the principle register in the United States Patent and Trademark Office, and the use of which mark was likely to cause confusion, mistake and deception regarding said mark.

**In violation of Title 18, United States Code, Sections 2320(a) and 2.**

**COUNT SEVEN**  
**(Trafficking in Counterfeit Goods)**

1. On or about February 20, 2007, in the Houston Division of the Southern District of Texas, the defendant,

KEVIN XU

aided and abetted by others unknown to the Grand Jury, did intentionally traffic and attempt to traffic in goods, namely, pharmaceutical drugs, and knowingly used a counterfeit mark on and in connection with such goods, that is, the Plavix trademark used to identify a pharmaceutical product marketed by Bristol-Myers Squibb and Sanofi Aventis, which counterfeit mark was identical with and substantially indistinguishable from the genuine mark in use and registered for that good on the principle register in the United States Patent and Trademark Office, and the use of which mark was likely to cause confusion, mistake and deception regarding said mark.

**In violation of Title 18, United States Code, Sections 2320(a) and 2.**

**COUNT EIGHT**  
**(Trafficking in Counterfeit Goods)**

1. On or about April 13, 2007, in the Houston Division of the Southern District of Texas, the defendant,

KEVIN XU

aided and abetted by others unknown to the Grand Jury, did intentionally traffic and attempt to traffic in goods, namely, pharmaceutical drugs, and knowingly used a counterfeit mark on and in connection with such goods, that is, the Casodex trademark used to identify a pharmaceutical product marketed by Astra Zeneca Corporation, which counterfeit mark was identical with and substantially indistinguishable from the genuine mark in use and registered for that good on the principle register in the United States Patent and Trademark Office, and the use of which mark was likely to cause confusion, mistake and deception regarding said mark.

**In violation of Title 18, United States Code, Sections 2320(a) and 2.**

**COUNT NINE**  
**(Trafficking in Counterfeit Goods)**

1. On or about June 10, 2007, in the Houston Division of the Southern District of Texas, the defendant,

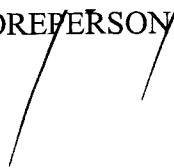
KEVIN XU

aided and abetted by others unknown to the Grand Jury, did intentionally traffic and attempt to traffic in goods, namely, pharmaceutical drugs, and knowingly used a counterfeit mark on and in

connection with such goods, that is, the Aricept trademark used to identify a pharmaceutical product marketed by Pfizer, which counterfeit mark was identical with and substantially indistinguishable from the genuine mark in use and registered for that good on the principle register in the United States Patent and Trademark Office, and the use of which mark was likely to cause confusion, mistake and deception regarding said mark.

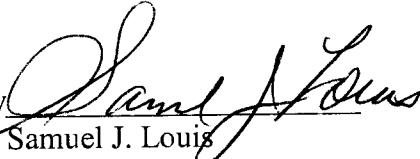
**In violation of Title 18, United States Code, Sections 2320(a) and 2.**

  
**Original Signature on File**

  
FOREPERSON

DONALD J. DeGABREILLE, JR.  
UNITED STATES ATTORNEY

by

  
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